

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 21101.0050P1	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/040824	International filing date (<i>day/month/year</i>) 06 December 2004 (06.12.2004)	Priority date (<i>day/month/year</i>) 04 December 2003 (04.12.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant UNIVERSITY OF UTAH RESEARCH FOUNDATION		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a):																
2.	This REPORT consists of a total of 4 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 07 June 2006 (07.06.2006) Authorized officer Simin Baharlou Telephone No. +41 22 338 71 30
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PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

02 FEB 2006

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

21101.0050P1

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/40824

06 December 2004 (06.12.2004)

04 December 2003 (04.12.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A01N 1/02; C12N 5/06 and US Cl.: 435/1.2, 1.3, 2, 325, 374

Applicant

UNIVERSITY OF UTAH RESEARCH FOUNDATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Date of completion of this opinion

06 January 2006 (06.01.2006)

Authorized officer

Vera Afremova

Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/40824

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/40824

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-29</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-29</u>	NO
Industrial applicability (IA)	Claims <u>1-29</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-12 and 17-29 lack novelty under PCT Article 33(2) as being anticipated by US 5,102,783 (Alkemade et al).

Claims are directed to a composition and/or kit comprising cells or tissues and glycosaminoglycan (GAG) in the absence of serum. Some claims are further drawn to the GAG such as hyaluronan. Some claims are directed to a method of making a cell-containing storage solution by utilizing GAG in the absence of serum. Some claims are directed to a method for preserving cells by utilizing GAG in the absence of serum at temperature above or below freezing. Some claims are directed to a method of treatment by utilizing GAG in the absence of serum and using cells.

US 5,102,783 (Alkemade et al) teaches composition, kit and methods for maintaining and preserving living tissues and cells including embryos and sperm cells without serum by substituting hyaluronic acid for serum products (see abstract; col. 2, lines 25-45; col.7, lines 54-57). Thus, the cited patent discloses identical composition, kit and methods within the meaning of claims.

Claims 1, 3-6, 8-11, 13-17, 19, 21 and 23 lack novelty under PCT Article 33(2) as being anticipated by US 5,728,405 (McDonnell).

Claims are directed to a composition and/or kit comprising cells or tissues and glycosaminoglycan (GAG) in the absence of serum. Some claims are directed to a method of making a cell-containing storage solution by utilizing GAG in the absence of serum. Some claims are directed to a method for preserving cells by utilizing GAG in the absence of serum at temperature above freezing. Some claims are directed to a method of treatment by utilizing GAG in the absence of serum and using cells.

US 5,728,405 (McDonnell) discloses a composition and/or kit comprising corneal epithelial cells and chondroitin sulfate as GAG in the absence of serum (col.5, lines 34-50; col. 6, lines 13-21) in the methods for storing corneal epithelial cells and preventing keratinocyte loss. Thus, the cited patent discloses identical composition, kit and methods within the meaning of claims.

Claims 1-29 lack an inventive step under PCT Article 33(3) as being obvious over US 5,102,783 (Alkemade et al) in view of US 5,728,405 (McDonnell) and US 6,548,297 (Kuri-harcuch et al).

Claims are directed to a composition and/or kit comprising cells or tissues and glycosaminoglycan (GAG) in the absence of serum. Some claims are further drawn to the GAG such as hyaluronan and to the use of various cells including epithelial cells. Some claims are directed to a method of making a cell-containing storage solution by utilizing GAG in the absence of serum. Some claims are directed to a method for preserving cells by utilizing GAG in the absence of serum at temperature above or below freezing. Some claims are directed to a method of treatment by utilizing GAG in the absence of serum and using cells.

US 5,102,783 (Alkemade et al) teaches composition, kit and methods for maintaining and preserving living tissues and cells without serum by substituting hyaluronic acid for serum products. The living cells and tissues include but not limited embryos, sperm and unfertilized ova (col. 2, lines 51-55).

Further, US 5,728,405 (McDonnell) demonstrate beneficial application of GAG for maintaining integrity and viability of corneal epithelium at temperature above freezing. The cited US 6,548,297 (Kuri-harcuch et al) teaches and suggests the use of hualyronic acid as cryoprotective agent (col. 6, line 50) for cryopreservation of epithelial cells intended fro wound healing (col.4, lines 20-33).

Therefore, the claimed invention lacks inventive step because composition, kit and methods for maintaining and preserving various living tissues and cells without serum by substituting hyaluronic acid for serum products is known in the prior art as adequately demonstrated by US 5,102,783 (Alkemade et al) in view of US 5,728,405 (McDonnell) and US 6,548,297 (Kuri-harcuch et al).